



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2019-N-1250]

General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to reclassify surgical staplers for internal use (currently regulated under the classification for “manual surgical instrument for general use” and assigned the product code GAG) from class I (general controls) into class II (special controls) and subject to premarket review. FDA is identifying the proposed special controls for surgical staplers for internal use that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. As part of this reclassification, FDA is also proposing to amend the existing classification for “manual surgical instrument for general use” to remove staplers and to create a separate classification regulation for surgical staplers that distinguishes between surgical staplers for internal use and external use.

DATES: Submit either electronic or written comments on the proposed order by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN *FEDERAL REGISTER*]. Please see section XI of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-N-1250 for “General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers.”

Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact

information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: R. Dale Rimmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G425, Silver Spring, MD 20993, 240-402-4828, ralph.rimmer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments (Medical Device Amendments of 1976, Pub. L. 94-295), May 28, 1976 (generally referred to as “preamendments devices”), are classified after FDA has: (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976 (generally referred to as “postamendments devices”), are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless, and until: (1) FDA reclassifies the device into class I or II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807, subpart E of the regulations (21 CFR part 807).

On July 9, 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 513(e)(1)(A)(i) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of an administrative order reclassifying a device, the following must occur: (1) publication of a proposed reclassification order in the *Federal Register*, (2) a meeting of a device classification panel described in section 513(b) of the FD&C

Act, and (3) consideration of comments to a public docket. The proposed reclassification order must set forth the proposed reclassification and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risks of the device.

Section 513(e)(1)(A)(i) provides that FDA may, by administrative order, reclassify a device based on “new information.” FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA. The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos v. United States Dep’t of Health, Educ. & Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn Co. v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966)) or in light of changes in “medical science” (see *Upjohn Co. v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the “new information” to support reclassification under section 513(e) of the FD&C Act must be “valid scientific evidence”, as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid

scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (see section 520(c) of the FD&C Act).

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of surgical staplers for internal use. Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

II. Regulatory History of the Devices

Surgical staplers were classified in part 878 (21 CFR part 878) in a final rule published in the *Federal Register* on June 24, 1988 (53 FR 23856), that classified 51 general and plastic surgery devices. This 1988 rule classified staplers into class I (general controls). These devices were grouped with other devices under “Manual surgical instrument for general use” in § 878.4800 (21 CFR 878.4800). At the time, surgical staplers had been in common use in medical practice for many years, and FDA believed that general controls were sufficient to provide reasonable assurance of the safety and effectiveness of those devices. This rule was amended on April 5, 1989 (54 FR 13826), to clarify that manual surgical instruments for general use, § 878.4800, made of the same materials as used in the preamendments devices were exempt from premarket notification (510(k)) review.

On December 7, 1994, FDA further amended the classification when it published a final rule in the *Federal Register* (59 FR 63005) that exempted 148 class I devices from premarket

notification, with limitations. Surgical staplers were one of those exempted devices. FDA determined that manufacturers' submissions of premarket notifications were unnecessary for the protection of the public health and that FDA's review of such submissions would not advance its public health mission.

On March 8, 2019, FDA issued a letter to healthcare providers to inform them of the risks associated with misuse of surgical staplers and to provide recommendations for reducing the risk of adverse events associated with these devices (Ref. 1). This letter recommends that users carefully follow the stapler manufacturer's instructions for use and provides additional recommendations for selecting the appropriate staple sizes and tissue types appropriate for use with the stapler.

Elsewhere in this issue of the *Federal Register*, FDA is publishing a notice of availability for a draft guidance entitled "Surgical Staplers and Staples for Internal Use--Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff." As identified in this draft guidance, FDA has become aware of a large number of adverse events associated with surgical staplers and staples for internal use. This draft guidance communicates FDA's recommendations for contraindications, warnings, directions for use, and technical characteristics and performance parameters to be included in the product labeling to help promote the safe and effective use of surgical staplers and staples for internal use. This draft guidance also provides recommendations for content to be included in the package labels, so that users may easily look at the label and obtain critical information necessary for proper device selection.

Surgical staples are currently regulated as class II devices under 21 CFR 878.4750 (Implantable staple) and are subject to premarket notification (510(k)) review. FDA does not

intend to change the classification of surgical staplers at this time and they are outside the scope of this reclassification action.

III. Device Description

A surgical stapler is a specialized prescription device used to deliver compatible staples during surgery. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

To delineate between surgical staplers and their intended uses, FDA has identified two subsets of surgical staplers: (1) surgical staplers for internal use and (2) surgical staplers for external use.

A surgical stapler for internal use is a specialized prescription device used to deliver compatible staples to internal tissues during surgery for removing part of an organ (i.e., resection), cutting through organs and tissues (i.e., transection), and creating connections between structures (i.e., anastomoses). It may be used in open, minimally invasive, and endoscopic surgery. Surgical staplers for internal use may be indicated for use in a wide range of surgical applications, including, but not limited to, gastrointestinal, gynecologic, and thoracic surgery.

Many types of surgical staplers for internal use exist, including, but not limited to, linear non-cutting staplers, transverse approximating staplers, transverse anastomoses staplers, gastrointestinal anastomoses linear cutting (articulating and non-articulating) staplers, and circular (i.e., end-to-end anastomoses) staplers. Surgical staplers for internal use include both manual and powered staplers.

A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery. FDA is proposing to reclassify internal staplers only; external staplers will remain class I, exempt from premarket review.

IV. Proposed Reclassification

FDA is proposing to reclassify surgical staplers for internal use from class I (general controls), exempt from premarket review, to class II (special controls), subject to premarket review. FDA believes that general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices, and that there is sufficient information to establish special controls to provide such assurance. In accordance with section 513(e)(1)(A)(i) of the FD&C Act, FDA, on its own initiative, is proposing to reclassify these devices based on new information. The process for issuing a final order for reclassification of a device from class I to class II pursuant to section 513(e) of the FD&C Act is provided in 21 CFR 860.130 of the regulations. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) publication of a proposed reclassification order in the *Federal Register*; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. The Commissioner of Food and Drugs is required to consult with a classification panel and may secure a recommendation with respect to the reclassification of the device. FDA will consult with the panel regarding the reclassification of the device in accordance with the procedures set forth in 21 CFR 860.125 and intends to secure the panel's recommendation. If FDA issues a final order, the Agency will publish the panel's recommendation in the *Federal Register* when the Agency publishes the final order.

FDA is also proposing to revise § 878.4800 (Manual surgical instrument for general use) to remove staplers and to create a separate classification regulation in part 878 for surgical staplers that distinguishes between surgical staplers for internal use and external use.

V. Public Health Benefits and Risks to Health

As required by section 513(e)(1)(A)(i) of the FD&C Act, FDA is providing a substantive summary of the valid scientific evidence concerning the proposed reclassification including the public health benefit of the use of surgical staplers for internal use, and the nature, and if known, the incidence of the risk of the devices, as discussed in section VI of this proposed order.

Surgical staplers for internal use provide benefit to the public health by facilitating surgical procedures and allowing for shorter surgical procedure times compared to manual suturing.

FDA has evaluated the risks to health associated with the use of surgical staplers for internal use and has identified the following risks for this device:

- *Complications associated with device failure/malfunction.* Device failures or malfunctions may result in prolonged surgical procedures, unplanned surgical interventions, and other complications such as bleeding, sepsis, fistula formation, tearing of internal tissues and organs, increased risk of cancer recurrence, and death.
- *Complications associated with use error/improper device selection and use.* Use error may result from a device design that is difficult to operate and/or labeling that is difficult to comprehend. For example, user difficulty in firing the stapler may result in staples not being fully deployed, and misfiring may result in staples being inadvertently applied to the wrong tissue. Inadequate instructions for use may result in selection of incorrectly sized staples for the target tissue. When staples are applied to the wrong tissue or when

incorrectly sized staples are applied, staples are unable to properly approximate the underlying tissue, resulting in tissue damage, anastomotic leakage, and bleeding. This in turn, may lead to more severe complications, such as abscess, sepsis, peritonitis, hemorrhage, or death.

- *Adverse tissue reaction.* If the patient-contacting materials of the device are not biocompatible, local tissue irritation and sensitization, cytotoxicity, or systemic toxicity may occur when the device contacts sterile tissue.
- *Infection.* If the device is not adequately reprocessed or sterilized, the device may introduce pathogenic organisms into sterile tissue and may cause an infection in a patient.

As discussed further in this document, these findings regarding the public health benefits and risks to health associated with surgical staplers for internal use are based on publicly available information, including Medical Device Reporting (MDR) analyses, recalls, and the published literature.

VI. Summary of Data Upon Which the Reclassification Is Based

Surgical staplers for internal use have been shown to provide several benefits over manual suturing, including reduction in surgical time, reduced tissue trauma/manipulation, reduction in surgical contamination by intestinal contents, and simple closure of vessels and/or tissues (Ref. 2); however, they have also been associated with numerous adverse events.

As discussed below, based on a review of the MDR database, recalls database, and the published scientific literature, there have been many malfunctions and other problems associated with surgical staplers for internal use, and some of these malfunctions or other problems have been associated with serious complications, including death.

Because surgical staplers are used together with staples as a system, a search of the MDR database was conducted for both surgical staplers for internal use under product code GAG (Stapler, Surgical) and surgical staples for internal use under product code GDW (Staple, Implantable) to obtain a comprehensive picture of the safety profile for surgical staplers for internal use. From January 1, 2011, to March 31, 2018, FDA received over 41,000 individual MDRs for surgical staplers and staples for internal use, including 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. Some of the most commonly reported problems in these adverse event reports include an opening of the staple line or malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to tissue). Although the majority of the adverse events were reported under product code GDW, FDA believes that many of the problems identified in these reports can be primarily attributed to surgical staplers for internal use, since proper staple formation is largely contingent on proper function and use of the stapler.

Of the 366 deaths, the cause of death was associated with an opening of the staple line or malformation of staples in 159 reports, bleeding during surgery in 53 reports, sepsis in 47 reports, peritonitis in 5 reports, necrosis in 5 reports, and air embolism in 4 reports. Additionally, of the 366 deaths, 195 reports included misfiring, difficulty in firing, and/or misapplied staples. Common reasons cited for these problems included mechanical issues with the device (e.g., mechanical jams), broken device components, and the device operating differently than the user expected (e.g., different force needed to deploy the device than expected). In 11 of the 366 deaths, use error was determined to be a contributing factor to the death. Many of the same complications that resulted in death (e.g., bleeding during surgery,

peritonitis, and sepsis) were also reported in the serious injury reports; additional complications commonly reported in the serious injury reports included tissue damage, organ perforation or dehiscence, fistula formation, infection, hernia, and pain.

The majority of staplers reported in these adverse events were linear staplers, including articulating and curved tip linear staplers, followed by circular staplers. Of the 366 deaths, 262 deaths were reported for linear staplers while 63 were reported for circular staplers; of the remaining 41 deaths, a type of stapler was not identified in the MDR. The staplers involved in these adverse events spanned a variety of different manufacturers; there were no distinct differences between manufacturers and the reported causes of death.

Of the 41,000 individual MDRs, over 32,000 MDRs were received for malfunctions, under either the product code GAG (Stapler, Surgical) or product code GDW (Staple, Implantable). The most common device-related malfunctions included failure of the stapler to fire the staple, failure to form staples, difficulty of opening/closing the stapler, stapler misfiring, and stapler breakage. The most commonly reported patient consequences from malfunctions with surgical staplers for internal use included a delay in surgical procedure, hemorrhage, and tissue damage. It should be noted that some patient consequences may not be limited to a single reporting category of death, serious injury, or malfunction. For example, a malfunction could result in sepsis, which could lead to other serious injury and later death.

The types and incidence of malfunctions and clinical consequences to patients seen in the adverse event reports are also corroborated by the published literature. In a systematic review of 30 clinical studies (Refs. 3 to 32), including randomized controlled trials and observational studies, the occurrence of stapler malfunctions in these studies ranged from incidents in 0 to 19.2 percent (median = 1.8 percent) of patients and 0.1 to 5.2 percent of deployments.

Consistent with the malfunctions seen in the adverse event reports received by FDA, the most common malfunctions reported in these clinical studies were related to opening of the staple line or malformation of staples. In these studies, malformed staples and/or staple lines comprised 31.8 percent of the malfunctions, while missing staples and/or staple lines not forming comprised 19.5 percent of the malfunctions. Problems with stapler firing and/or stapler function were also commonly reported. Device sticking, locking, and/or jamming comprised 15.9 percent of the malfunctions, while stapler misfiring comprised 10.3 percent of the malfunctions. Inability of the stapler to cut through tissue comprised 3.1 percent of the malfunctions, while stapler breakage comprised 2.6 percent of all malfunctions. Finally, problems with the stapler cartridge not loading properly comprised 2.1 percent of the malfunctions. Although the majority of studies in the systematic literature review did not report on the incidence of stapler problems associated with use error, a prospective, single-arm study evaluating use of a surgical stapler in gastrointestinal stapling applications found that 3.5 percent of stapler deployments in the study (15 of 423 deployments) were attributed to use error (Ref. 10). Additionally, as discussed further below, common causes for surgical complications reported in the literature include use error.

While 75.8 percent of the stapler malfunctions in these studies did not result in any major consequences to the patient, 10.5 percent of the malfunctions resulted in the need to convert to open surgery, while 9.7 percent of the malfunctions resulted in hemorrhage; 4.0 percent of the malfunctions resulted in both hemorrhage and the need to convert to open surgery. In addition, multiple studies suggest that surgical stapler malfunctions are associated with a higher risk of complications. In a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions (Ref. 27). In a

retrospective study of 1,174 patients undergoing liver transections using a stapler device, surgeries with surgical stapler malfunctions were found to have a higher likelihood of transfusion, higher median blood loss, and higher odds of morbidity and mortality compared to surgeries without stapler malfunctions (Ref. 28). Anastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence (Refs. 33 to 35). Altogether, the adverse event reports and published literature indicate that surgical stapler malfunctions are not uncommon and may produce adverse outcomes such as conversion to open surgery, bleeding, morbidity, and death.

Common causes for surgical complications reported in the literature also include the use of incorrectly sized staples for the tissue, incorrect use of the device by the user, and improper use of the device for the condition of the patient's tissues, which may result in reoperation or prolonged hospitalization (Ref. 36). For example, early postoperative anastomotic leak due to such device issues may result in a septic patient with peritonitis, requiring immediate surgery with diversion of stool into a stoma. Minor or delayed anastomotic leaks due to such device issues may result in an intra-abdominal abscess requiring surgical or other invasive drainage procedures, temporary diversion of stool, and prolonged intravenous nutrition. These complications commonly result in prolonged hospital stays (Ref. 37). Altogether, the adverse event reports and published literature indicate that surgical stapler for internal use use error may cause or contribute to surgical complications, e.g., anastomotic leaks, abscess, sepsis, peritonitis, and death.

From November 1, 2002, to December 30, 2018, FDA received a total of 168 recalls for surgical staplers and staples for internal use under product codes GAG and GDW, including one class I recall and 167 class II recalls. The class I recall was for a hemorrhoidal circular stapler

that may result in incomplete staple formation due to difficulty in firing. Of the 167 class II recalls, the most common reasons for recall included non-conforming device components or device design-related issues that may result in incomplete staple formation, failure to form a staple line, malformed staples, or difficulty in firing. Several devices were also recalled due to a potential breach in sterility.

FDA acknowledges that the available valid scientific evidence, including the review of the MDR database, recalls database, and the published literature, primarily discuss surgical staplers for internal use, and not surgical staplers for external use. At this time, FDA does not believe that available information suggests that reclassification of surgical staplers for external use is necessary to maintain a reasonable assurance of safety and effectiveness of these devices.

Based on its review of the MDR database, recalls database, and the published literature, FDA has tentatively determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for surgical staplers for internal use. FDA believes the establishment of special controls is necessary to ensure that the risks to health are adequately mitigated by an assessment of these devices through completion of performance testing, usability and labeling comprehension testing, biocompatibility evaluation, sterility and shelf-life testing, and adequate labeling. In addition, FDA believes that design controls under 21 CFR 820.30 are necessary to ensure that specified design requirements are met and to ensure compatibility of surgical staplers for internal use with staples. Therefore, FDA, on its own initiative, is proposing to reclassify these devices from class I into class II (special controls) subject to premarket review.

VII. Summary of Reasons for Reclassification

Based on the information reviewed by FDA, including the valid scientific evidence regarding the public health benefit and nature and incidence of the risk of the devices discussed in section VI, FDA tentatively concludes that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for surgical staplers for internal use. Therefore, FDA proposes to reclassify surgical staplers for internal use from class I into class II (special controls).

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are necessary and sufficient to mitigate the risks to health described in section V (complications associated with device failure/malfunction, complications associated with use error/improper device selection and use, adverse tissue reaction, and infection) and provide a reasonable assurance of safety and effectiveness for surgical staplers for internal use.

Both device misuse and device malfunctions are root causes of the adverse events associated with use of surgical staplers for internal use (Ref. 38). Device misuse may be exacerbated by inadequate instructions for use and insufficient warnings or precautions in the device labeling (Ref. 39). To mitigate the risks of tissue damage, anastomotic leakage, and bleeding arising from use error or improper device use, FDA believes that the labeling must include specific instructions for device use, including procedures associated with proper device use and measures for preventing device malfunction, evaluating the appropriateness of the target tissue for stapling, and evaluating the resultant staple line. To further mitigate these risks, the labeling must also include appropriate warnings, contraindications, and limitations needed for safe use of the device. To prevent stapler malfunction (e.g., from stapler jamming, locking, sticking, or misfiring), information on the staples with which the stapler is compatible must be

provided in the labeling, such as models of compatible staples, cartridge colors/staple heights, staple rows per cartridge, staple patterns, and maximum and minimum tissue thicknesses for each staple type. To prevent improper application of staples to target tissue, the recommended tissues (e.g., tissue thicknesses and tissue types) on which the stapler is intended to be used must be identified in the labeling. Unless data demonstrates the safety of doing so, contraindications must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of necrotic or ischemic tissues and tissues outside of the labeled limits of tissue thickness. The labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use, including avoidance of obstructions to the creation of a staple line (e.g., clips) and the unintended stapling of other anatomic structures; avoidance of clamping and unclamping of delicate tissue structures (e.g., venous structures and bile ducts) to prevent tissue damage; avoidance of use of the stapler on large blood vessels, such as the aorta; establishing and maintaining proximal control of blood vessels prior to stapling; appropriate measures to take if a stapler malfunction occurs while applying staples across a blood vessel, such as clamping or ligating the vessel before releasing the stapler, while the stapler is still closed on the tissue; and ensuring stapler compatibility with staples, unless information is provided demonstrating that the warnings do not apply to a particular device. Usability testing and a labeling comprehension study must demonstrate that the clinician can correctly select and use the device for its indicated use based on the information in the labeling.

To mitigate the risk of complications associated with device failure or device malfunction, adequate performance testing is needed to ensure that the stapler with compatible staples performs as intended under anticipated conditions of use. FDA believes that adequate

performance testing must include an evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type; measurement of the worst-case deployment pressures on stapler firing force; and a measurement of staple line strength. Performance testing must also demonstrate confirmation of staple line integrity (e.g., through the absence of vertically contiguous malformed staples), as well as in vivo confirmation of staple line hemostasis following staple deployment.¹

FDA believes that the inclusion of important technical characteristics and device performance parameters in the labeling will also help mitigate use error and device malfunctions by informing end users on device limitations. Therefore, FDA believes that the labeling must identify key technical characteristics and performance parameters of the surgical stapler and compatible staples needed for safe use of the device. Key technical characteristics include stapler specifications (e.g., jaw length, shaft length, jaw opening, and angles of articulation), as well as compatible staple specifications (e.g., open and closed staple heights). Key technical characteristics also include identification of any safety mechanisms of the stapler, such as a color-firing zone and/or lock-out mechanism. Examples of key performance parameters include information on firing the stapler, such as the firing force, pre-fire compression time, and maximum number of consecutive firings, and information relevant to creating a staple line, such as the percentage of properly formed staples, number of incremental firings required to complete a staple line, and maximum number of reloads.

FDA believes that the device must be demonstrated to be biocompatible because the risk of adverse tissue reaction may result from contact of the materials of the device with the body.

¹ FDA supports the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. FDA encourages sponsors to consult with FDA if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. FDA will consider if such an alternative method could be assessed for equivalency to an animal test method.

Additionally, because the risk of infection can arise from a contaminated device, sterility testing must demonstrate the sterility of the device. If any components of the device are reusable, the labeling must include validated methods and instructions for cleaning and sterilization of these reusable components. Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

In addition, loss of package integrity can result in compromised sterility and compromised device performance over time. Therefore, shelf-life testing must demonstrate that the device maintains its performance characteristics and the packaging of the device maintains its integrity for the duration of the proposed shelf-life. Finally, the labeling must also specify an expiration date to inform users of the shelf-life of the device based on the shelf-life testing.

Table 1 shows how FDA believes each risk to health described in section V would be mitigated by the proposed special controls.

Table 1.--Risks to Health and Mitigation Measures for Surgical Staplers for Internal Use

Identified Risks to Health	Mitigation Measures
Complications associated with device failure/malfunction	Performance testing and Labeling
Complications associated with use error/improper device selection and use	Usability testing, Labeling comprehension study, and Labeling
Adverse Tissue Reaction	Biocompatibility evaluation
Infection	Labeling, Sterility testing, and Shelf-Life testing

If finalized, the reclassification of surgical staplers for internal use into class II would subject these devices to premarket notification under section 510(k) of the FD&C Act and part 807, subpart E, and the identified special controls in this order. FDA believes that the proposed

reclassification would provide reasonable assurance of safety and effectiveness of surgical staplers for internal use.

IX. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520) is not required. This proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

XI. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective on its date of publication in the *Federal Register*.

- Surgical staplers for internal use that have not been offered for sale prior to the effective date of the final order or have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81(a)(3): Manufacturers would have to obtain 510(k)

clearance before marketing their devices after the effective date of the order. If a manufacturer markets such a device without receiving 510(k) clearance, then FDA would consider taking action against such a manufacturer under its usual enforcement policies.

- Surgical staplers for internal use that have been offered for sale prior to the effective date of the final order and do not already have 510(k) clearance: FDA does not intend to enforce compliance with the 510(k) requirement or special controls until 180 days after the effective date of the final order. After that date, if a manufacturer continues to market such a device but does not have 510(k) clearance or FDA determines that the device is not substantially equivalent or not compliant with special controls, then FDA would consider taking action against such manufacturer under its usual enforcement policies.

For surgical staplers for internal use that have prior 510(k) clearance, FDA would accept a new 510(k) and would issue a new clearance letter, as appropriate, indicating substantial equivalence and special controls compliance. These devices could serve as predicates for new devices. These clearance letters would be made publicly available in FDA's 510(k) database, and compliance with special controls at the time of clearance would also be stated in the publicly available 510(k) Summary posted in this database. FDA believes that our public database is a transparent tool allowing users to confirm that their devices have been submitted under a new 510(k) and demonstrated conformance to applicable special controls.

XII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, it also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the

Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in the proposed order, we are proposing to revoke the classification of surgical staplers in § 878.4800 and to codify surgical staplers in the new 21 CFR 878.4740, under which surgical staplers for internal use would be reclassified into class II and surgical staplers for external use would remain in class I.

XIII. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; references with website addresses are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 878.4740 to subpart E to read as follows:

§ 878.4740 Surgical stapler.

(a) *Surgical stapler for external use.* (1) *Identification.* A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

(b) *Surgical stapler for internal use.* (1) *Identification.* A surgical stapler for internal use is a specialized prescription device used to deliver compatible staples to internal tissues during surgery for resection, transection, and creating anastomoses.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) Performance testing must demonstrate that the stapler, when used with compatible staples, performs as intended under anticipated conditions of use. Performance testing must include the following:

(A) Evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type;

(B) Measurement of the worst-case deployment pressures on stapler firing force;

(C) Measurement of staple line strength;

(D) Confirmation of staple line integrity; and

(E) In vivo confirmation of staple line hemostasis.

(ii) Usability testing and a labeling comprehension study must demonstrate that the clinician can correctly select and use the device, as identified in the labeling, based on reading the directions for use.

(iii) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(iv) Performance data must demonstrate the sterility of the device.

(v) Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

(vi) Performance data must support the shelf life of the device by demonstrating continued device functionality, sterility, and package integrity over the identified shelf life.

(vii) Labeling of the device must include the following:

(A) Unless data demonstrates the safety of doing so, contraindications must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of necrotic or ischemic tissues and tissues outside of the labeled limits of tissue thickness.

(B) Unless available information demonstrates that the specific warnings do not apply, the labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use including:

(i) Avoidance of obstructions to the creation of the staple line and the unintended stapling of other anatomic structures;

(ii) Avoidance of clamping and unclamping of delicate tissue structures to prevent tissue damage;

(iii) Avoidance of use of the stapler on large blood vessels, such as the aorta;

(iv) Establishing and maintaining proximal control of blood vessels prior to stapling;

(v) Appropriate measures to take if a stapler malfunction occurs while applying staples across a blood vessel, such as clamping or ligating the vessel before releasing the stapler, while the stapler is still closed on the tissue; and

(vi) Ensuring stapler compatibility with staples.

(C) Specific user instructions for proper device use including measures associated with the prevention of device malfunction, evaluation of the appropriateness of the target tissue for stapling, and evaluation of the resultant staple line.

(D) List of staples with which the stapler has been demonstrated to be compatible.

(E) Identification of key performance parameters and technical characteristics of the stapler and the compatible staples needed for safe use of the device.

(F) Information regarding tissues on which the stapler is intended to be used.

(G) Identification of safety mechanisms of the stapler.

(H) Validated methods and instructions for reprocessing of any reusable device components.

(I) An expiration date/shelf life.

(viii) Package labels must include critical information and technical characteristics necessary for proper device selection.

3. In § 878.4800, revise paragraph (a) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.

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Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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